ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

November 14, 2007

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. von Eschenbach:

We are concerned about the Food and Drug Administration's (FDA) use of its limited enforcement resources and the adequacy of its dispute resolution process. Our concerns arise in part from FDA's effort to resolve a routine compliance issue with a small medical device company by having the Center for Devices and Radiological Health (CDRH) pursue a multi-year enforcement action rather than a quick and efficient dispute resolution. We wrote to you on April 12, 2007, about warning letters issued by the CDRH/FDA in this matter. The FDA replied to us on July 26, 2007, and briefed Minority Committee staff on August 13, 2007.

We question whether the greatest public health impact is being achieved by FDA pursuing a protracted dispute with a small company rather than using good-faith dispute resolution. The case involves a four-year-old dispute over a medical device firm not submitting 17 reports, for which FDA is seeking $10,000 per violation and $510,000 in total civil money penalties. This is one of only 10 cases in the last 10 years in which FDA has sought civil money penalties. Of the other nine cases, seven cases were settled. One case which was partially settled involved penalties of $3,000 per violation of the Mammography Quality Standards Act that involved 1,201 mammography examinations. In the case still being litigated, FDA is seeking $3,000 per violation involving 192 mammograms.

We raise this matter to call your attention to past and continuing oversight concerns with FDA: the Agency's failure to set priorities, poor communication between the Agency and regulated industry, and continued management weakness. As far back as 1995, at hearings held before the Subcommittee on Oversight and Investigations, case studies presented included an impasse over a product review issue between a small medical device company and CDRH that persisted over a decade. At that time, Ranking

Member John D. Dingell suggested periodic reporting and evaluation of management designed to catch small difficulties before these matters reached the stage of irritating and embarrassing problems. Then FDA Commissioner David Kessler replied: "I think there was an impasse here. You are 100 percent right. When that impasse hit top management early on we should have worked better to resolve that impasse." [Allegations of FDA Abuses of Authority, Hearings before the Subcommittee on Oversight and Investigations of the Committee on Commerce, House of Representatives, Serial No. 104-51, p. 107 (July 25, November 15, and December 5, 1995)].

After these hearings and the passage of the FDA Modernization Act of 1997, we in Congress had reason to believe that CDRH Directors would appropriately oversee and supervise problem cases. In light of recent medical device recalls and the relatively high (about 30%) percentage of FDA-regulated imports that are medical devices, it is not unreasonable to believe CDRH top management would intervene early in a compliance dispute to resolve an impasse over a sponsor's failure to file certain reports. With the case at issue, the controversial relationship between the firm and CDRH was well known to CDRH top management because they had approved the firm's devices in 2002, although the review team recommended that the firm's application not be approved. After the approval decision, the review team and an official from the first level of FDA management wrote "respectful disagreement memos." We understand from Minority Committee staff that there is little evidence of early supervision and involvement by CDRH top management aimed at expeditiously resolving the impasse in the case at issue.

FDA's July 26, 2007, letter to us also raises serious questions as to whether persons outside the Agency can have confidence that FDA will engage in good-faith dispute resolution and not use the dispute resolution process as a way to string individuals or companies along while FDA is actually preparing an enforcement action. In the case at issue, the CDRH Director upheld a warning letter sent to the firm, advised the firm that it could appeal to the FDA Commissioner, but then qualified that an appeal would not forestall an intervening enforcement action by FDA. The July 26 letter to us confirms FDA's view that the FDA regulation allowing persons outside FDA to seek review of an Agency decision or action is contingent on whether FDA prefers to pursue enforcement action. As presented in the letter, FDA's interpretation of its regulations leaves the dispute resolution process totally at FDA's discretion in every single case where dispute resolution is sought. CDRH's guidance on dispute resolution, however, claims "[p]ersons who disagree with a CDRH/FDA decision or action and wish to have it reviewed and reconsidered have a broad array of dispute resolution processes from which to choose." As presented in the guidance, the appeal options are not qualified by FDA enforcement action.

We also observe that the Commissioner's office not only refused to hear the firm's appeal, but did not respond until eight months after the request, and three days after the administrative complaint for civil monetary penalties was filed. When questioned by Minority Committee staff about events at FDA during the eight-month period between the appeal request and the filing of the complaint, FDA does not contest

that the official in the Commissioner's office designated to handle the appeal was advised on how to respond to the firm's request for appeal by the same FDA counsel who prepared the administrative complaint. The letter from the Commissioner's office relied on this complaint as a basis for refusing the appeal. While not in violation of the Administrative Procedures Act, this apparent ex parte contact does not give the appearance of a fair and impartial appeals process.

We request that you personally review how Center Directors monitor top disputes and controversies, and report back on management performance in this area and whether any further steps or actions will be taken to improve dispute resolution and priority-setting of enforcement resources. Given the nature and history between FDA and small medical device companies, particular attention should be paid to the CDRH. We also request that the FDA clarify its policies governing dispute resolution by defining situations where FDA will pursue dispute resolution in good faith without qualification.

We would appreciate a report on your findings and recommendations by December 14, 2007. If you have any questions, please contact Alan Slobodin of the Minority Committee Staff at (202) 225-3641.

Sincerely,

Joe Barton
Ranking Member
Committee on Energy and Commerce

Ed Whitfield
Ranking Member
Subcommittee on Oversight and Investigations

cc: The Honorable John D. Dingell, Chairman
The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations